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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,303	01/26/2007	Hiromi Matsuzaki	P30093	5121

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
05/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,303	MATSUZAKI ET AL.	
	Examiner	Art Unit	
	Megan Wolf	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/4/10 have been fully considered but they are not persuasive. Applicant argues that Carrison discloses sides 144 and 152 having a predetermined angle of 57º or 58º rather than the claimed angle of 20º-40º. However, one may consider sides 140 and 144 "a pair of opposite, non-parallel sides", in which case side 144 is inclined at a predetermined angle of 32 or 33º with respect to side 140.

Regarding the specific length of each side, applicant argues that Shimp fails to disclose at least two differing lengths. This argument is not persuasive because the main reference, Carrison, specifically discloses pellets having a plurality of edges having different lengths (fig.3). Carrison does not, however, specifically disclose the lengths of each side. Shimp was relied upon to teach the general size of pellets used in packing a bone defect. Shimp teaches pellets having lengths of up to about 4mm for the purpose of providing an injectable load bearing support at the repair site (par.10). Therefore in modifying Carrison in view of Shimp, one of ordinary skill in the art would have found it obvious to maintain the shape of Carrison, which has an inclined surface and sides having different lengths, but specify a size of about 4mm as taught by Shimp in order to provide the pellets in a size suitable for injection, which both Carrison and Shimp use to insert the pellets.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 14, and 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7,238,209 in view of Kim et al. 5,645,596 (hereafter referred to as Kim) and

in further view of Tofighi et al. 2003/0052829 (hereafter referred to as Tofighi). The claims of the application are not patentably distinct from the claims of the patent because they would have been obvious in view of the patent claims and in further view of Kim and Tofighi. Claims 1-15 of the patent only differ from the present claims because the present claims define a porosity of equal to or less than 75% and a collapsing strength of more than 15MPa.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein calcium phosphate is used as an implant material for the purpose of its spontaneous adhesion to the associated vertebrae, and wherein the porosity of the calcium phosphate is preferably between 30 and 45% for the purpose of simultaneously providing mechanical strength and promoting tissue ingrowth (col.4, ll.32-46).

Tofighi teaches a calcium phosphate compound for use in an implant, in the same field of endeavor, wherein the final porous calcium phosphate compound has a compression strength of greater than 20MPa for the purpose of being useful as a weight bearing implant material (par.56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the porosity of the pellets be less than 75% and the collapsing strength of the pellets be more than 15 MPa in view of Kim and Tofighi in order to provide a material that is capable of providing strength while promoting tissue ingrowth.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-8, 14, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrison et al. 2005/0038517 (hereafter referred to as Carrison) in view of Shimp 2004/0052829 (hereafter referred to as Shimp) in further view of Kim et al. 5,645,596 (hereafter referred to as Kim) and in further in view of Tofighi et al. 2003/0120351 (hereafter referred to as Tofighi).

Re claim 1, Carrison discloses the invention substantially as claimed including a bone replacement material to be used by being packed into a bone defective part, wherein the bone replacement material is a rigid biocompatible material (par.45) and is formed into a pellet wherein the pellet has a roughly polyhedral shape and is defined by a plurality of surfaces including a pair of opposite, non-parallel surfaces 140 and 144, one of the opposite, non-parallel surfaces being inclined at a predetermined angle in the range of 20 to 40º with respect to the other of the opposite, non-parallel surfaces (fig.3). The bone replacement material is also capable of being used in the manner claimed wherein each pellet is inserted into the hollow passage of the cylindrical member such that the inclined surface of the pellet faces the inclined surface of an adjacent pellet and the pellets are pushed out in various directions. Carrison discloses porous pellets that have a longest edge, a shortest edge, and a volume, but does not disclose the specific size of these dimensions wherein the longest edge is in the range of 5-10 mm, the shortest edge is in the range of 2-5 mm and the volume is in the range of 13 to 239 mm^3 or that the material consists essentially of calcium phosphate.

Shimp teaches bone replacement pellets, in the same field of endeavor, wherein the pellets are formed of porous calcium phosphate for the purpose of resisting deformation or fracture under the physiologic loads normally experienced at the repair site (pars.28-30), and wherein the pellets can vary in size but are preferably up to about 4mm (yielding a volume of about 64mm^3), for the purpose of providing an injectable load bearing support at the repair site (par.10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate for the implant material in order to provide an implant material that resists deformation or fracture under the physiologic loads normally experienced at the repair site. It would have been further obvious to specify the claimed size ranges for the pellets of Carrison as this size is best suited for injecting bone replacement material into a bone defect in the spine as taught by Shimp and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). While Carrison in view of Shimp discloses porous calcium phosphate pellets, Carrison in view of Shimp does not specifically disclose that the porosity is equal to or less than 75% and that the collapsing strength is equal to more than 15Mpa.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein calcium phosphate is used as an implant material for the purpose of its spontaneous adhesion to the associated vertebrae, and wherein the porosity of the calcium

phosphate is preferably between 30 and 45% for the purpose of simultaneously providing mechanical strength and promoting tissue ingrowth (col.4, ll.32-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate with a porosity of less than 75% as taught by Kim for the vertebral implants of Carrison in view of Shimp in order to allow for tissue ingrowth for anchoring the implant while maintaining mechanical strength to resist compression forces. As Kim discloses the claimed porosity as well as the Ca/P ratio claimed in claim 19, one would assume that the collapsing strength of the calcium phosphate compound of Kim is equal to or more than 15 MPa. Still, Carrison in view of Shimp in further view of Kim does not specifically state that the collapsing strength of the calcium phosphate based compound is 15MPa or more.

Tofighi teaches a calcium phosphate compound for use in an implant, in the same field of endeavor, wherein the final porous calcium phosphate compound has a compression strength of greater than 20MPa for the purpose of being useful as a weight bearing implant material (par.56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the calcium phosphate compound of Carrison in view of Shimp in further view of Kim have a collapsing strength greater than 15Mpa in order to provide a material that is strong enough for use as an implant that is required to bear weight as taught by Tofighi.

Re claims 2-4 and 14, see Carrison fig.3.

Re claims 5-8, while Carrison does not specifically disclose that the implant is either a pentahedral, cylindrical, or a triangular prism shape, these shapes are simply a matter of design choice and as it has been held that changes in shape are a matter of design choice, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B).

Re claim 19, see Kim col.4, ll.25-30.

Re claims 20 and 21, see Carrison figs. 13-18. Note that while Carrison does not disclose that the implants are inserted into the hollow passage of a cylindrical member such that the inclined surface of a pellet faces the inclined surface of an adjacent pellet, because of their shape shown in fig.3, the pellets of Carrison are capable of such use.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
/David H Willse/
Primary Examiner, Art Unit 3738